

TYCO HEALTHCARE GROUP LP v. MUTUAL PHARM. CO., Appeal No. 2013-1386 (Fed. Cir. August 6, 2014). Before Newman, Bryson, and Moore. Appealed from D.N.J. (Judge Chesler).

Background:

Tyco owns several patents directed to formulations or methods of treatment with a drug used to treat insomnia. The patents all claim 7.5 mg formulations of the drug having a specific surface area between 0.65 and 1.1 m²/g. Mutual filed an ANDA with the FDA, seeking approval of a generic 7.5 mg version of the drug, with a Paragraph IV certification that the generic product would not infringe Tyco's patents because the product would have a specific surface area of not less than 2.2 m²/g. Tyco filed an infringement suit.

The district court granted judgment of noninfringement, holding that the ANDA product could not literally infringe Tyco's patent. The next day, Tyco filed a citizen petition with the FDA urging the FDA to change the criteria for evaluating the bioequivalence of proposed generics of its drug. During the pendency of the citizen petition, the FDA approved Mutual's ANDA, and later formally denied Tyco's citizen petition in its entirety.

After the judgment of noninfringement, the trial continued with respect to Mutual's antitrust counterclaims, including (1) the patent litigation was a sham because Tyco's infringement claim was objectively baseless; and (2) the citizen petition was a sham. The district court granted summary judgment to Tyco on both of these antitrust counterclaims.

Issues/Holdings:

Did the district court err in granting summary judgment that Tyco did not violate antitrust laws by filing an infringement suit against Mutual and by filing the citizen petition with the FDA? Yes, vacated and remanded.

Discussion:

The majority vacated the district court's summary judgment that Tyco's infringement claims were not a sham. The majority confirmed that determination of whether a claim is objectively baseless requires a factual inquiry and therefore remanded the case for further consideration.

As to the citizen petition claim, the majority concluded that the district court erred in concluding that the sham exception to Noerr-Pennington immunity was expressly limited to litigation, ruling that it also applied to administrative petitioning, including FDA citizen petitions. The majority also found that there were disputed issues of fact that precluded summary judgment as to whether the citizen petition was objectively baseless. However, the majority questioned whether Mutual had proven any antitrust injury from the citizen petition. Thus, the majority indicated that the district court should determine whether Mutual suffered any injury in the form of a delay due to Tyco's filing of the citizen petition.

Judge Newman's dissent argued that the reversal creates several new grounds of antitrust liability that convert "routine patent litigation into antitrust violation."